Value of Trans-Impedance Matrix (TIM) measurement for detection of New Bone Formation (NBF) and influence on electrophysiology, residual hearing and performance.

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Primary Objective: Determine the value of trans-impedance measurement (TIM) for detection of new bone formation (NBF).Secondary Objective(s): Determine the influence of NBF on electrophysiological parameters, residual hearing and speech perception...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON48046

Source
ToetsingOnline

Brief title
TIM measurement for detecting NBF

Condition

- Hearing disorders

Synonym
New Bone Formation, severe-to-profound hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Cochlear Ltd,Cochlear Ltd. Benelux

Intervention

Keyword: Cochlear Implant, NBF, TIM

Outcome measures

Primary outcome

- Confirmation that NBF can reliably be detected using UHR CT-scan

- Confirmation the TIM measurement is useful to detect and monitor NBF

Secondary outcome

- Investigate co-registered changes of C-/T-levels in relation with NBF growth

- Confirm the influence of NBF on long term residual hearing

- Investigate electrode position and correlate with study outcomes

- Evaluate changes in performance over time possibly associated with NBF

Study description

Background summary

Cochlear tissue formation around the electrode of a cochlear implant is well known. Formation of scar tissue around the electrode of a cochlear implant can be either iatrogenic or resulting from a natural process. Iatrogenic scar tissue around the electrode can be induced by the *traumatic* insertion of the electrode array during surgery. Natural scar tissue is related to the reaction of the body to a foreign body by encapsulation of the object. It is believed that a dense tissue sheath around the electrode is problematic. In its most pronounced form, this tissue is ossified. This new bone formation (NBF) around the electrode has been observed in several animal and histopathological studies.1-4

In CI care, it is relevant to be able to detect the formation of a thick tissue layer for several reasons. First, the stimulation current will have to pass

through this tissue layer, adding additional resistivity. Higher impedances imply more power consumption and more out-of-compliance issues. This may impact device fitting, e.g. higher C-levels, longer pulse widths or in general poorer access to the neural tissue (in case of ossification). Second, the layer will influence the current spread through the cochlea, possibly leading to more channel interaction. Third, the NBF might influence long term loss of residual hearing. In a recently conducted cross sectional study (unpublished results) it was found that participants with presence of NBF (after an average follow-up time of 45 months) had significantly more loss of long term residual hearing compared to participants without NBF. Fourth and clinically most relevant, overall performance outcomes may be impacted directly or indirectly due to above factors.

In general, there is a desire to control and reduce the formation of a substantial tissue sheath. However before we can control, we need to be able to detect and monitor. The feasibility of detection has been demonstrated (manuscript in preparation) in a recent cross-sectional study where NBF was detected using an ultra high resolution computed tomography (UHRCT) scanner in the Radboudumc. A certain degree of NBF was seen in 61% of the 125 participants at an average follow-up of 3.8 years (SD 1.7; Range 1.2 - 7.7 years). A total of 2750 electrode contacts were judged to be surrounded with NBF or not; 13% of all contacts were found to have NBF around the electrode contact. In the same patient group, at the same moment, transimpedance measures (TIM) were taken. A first analysis showed that electrode contacts with NBF had higher values of total impedance compared to electrode contacts without NBF. The mean total impedance between contacts with / without NBF was respectively 7.468 (SD 2.022) and 5.863 (SD 2.362). This finding indicated that TIM measurements might be useful to detect and monitor NBF in CI patients. However, as indicated by the standard deviation, the variability of total impedance between contacts with and without NBF overlapped strongly; showing TIM measurements to depend on individual factors and, thus, vary greatly between patients.

The difference in mean total impedance might be explained by an (stronger) increase of TIM values in contacts with NBF compared to contacts without NBF. The most important limitation of the cross sectional study is the absence of a baseline TIM measurement (post implantation). To properly study the influence of NBF a prospective study should be conducted. This prospective study should include repetitive measurement of TIMs, to identify the increase of TIM values and to test the hypothesis that a degree of TIM growth is associated with NBF on long term imaging. With such a prospective study the hypothetical value of TIM to identify and monitor NBF growth can be shown. In the future, TIM measurements might be useful as a tool in NBF research and possibly as a clinical diagnostic tool.

Study objective

Primary Objective: Determine the value of trans-impedance measurement (TIM) for

detection of new bone formation (NBF).
Secondary Objective(s): Determine the influence of NBF on electrophysiological parameters, residual hearing and speech perception development.

Study design

A prospective study in patients that will receive a CI system and are willing to participate

Study burden and risks

Benefits of this study relay to an improved understanding and monitoring of postoperative intra-cochlear changes and the effect of these changes on residual hearing and performance, with possible implications for future therapy. Moreover, if the hypothesis that TIM is able to detect and monitor NBF is confirmed; in future studies, TIM can (partially) replace CT-scans and can be used to monitor studies with interventions against NBF

In this study, two additional post-operative UHR CT-scans of the temporal bone are required to monitor the NBF in participants. For those patients who for some reason do not receive a pre-operative UHR CT-scan, this will be performed as well. These UHR CT-scanners deliver a radiation load of 0.28 mSv per scan. In comparison, according to the RIVM, a CT-scan of the human brain delivers an average dose of 2.3 mSv, whilst a CT-scan of the abdomen delivers an average dose of 10.3 mSv. The worldwide annual average background radiation dose is approximately 2.6mSv.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients selected for cochlear implatation willing to participate (signed informed consent for study protocol)

Exclusion criteria

Patients unable to have a CT-scan
Patients with any anatomical situation influencing normal insertion

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2019

Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	27-08-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-09-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-02-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-04-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-02-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26583

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL70799.091.19
OMON	NL-OMON26583